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(54) Title: COSMETIC COMPOSITIONS			
(57) Abstract			
Cosmetic compositions containing as a preservative a polyhexamethylene biguanide salt and a buffer, the biguanide concentration being from 0.5 to 100 ppm.			

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## COSMETIC COMPOSITIONS

BACKGROUND OF THE INVENTION1. Field of the Invention:

5           This invention relates to cosmetic compositions and, more specifically, to such compositions containing an antimicrobial preservative.

10           Preservatives are desirable additions to cosmetic products for inhibiting the growth of microorganisms. In higher concentrations, certain substances also function as antiseptic or anti-fungal agents. Nevertheless, due to the ability to irritate the skin and create other dermatologic reactions, preservatives in cosmetic products  
15           must not exceed specific authorized concentrations. Examples of these preservatives include benzoic acid, salts and esters (0.5%), propionic acid and its salts (2%-acid) and polyhexamethylene biguanide hydrochloride (0.3%).

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2. Prior Art:

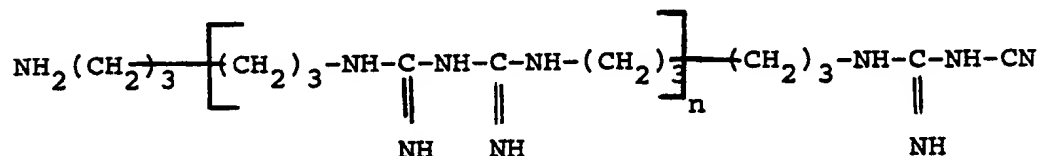
          Polyhexamethylene biguanide (also known as PHMB) has been disclosed as a preservative for cosmetic  
25           formulations. See the article entitled "Cosmetic Preservatives -- 1981", Cosmetics and Toiletries, Vol. 96, March, 1981, p 29 et seq. On page 30, the article includes the product "Cosmocil CQ" in a listing of cosmetic formulation preservatives. It is reported as  
30           being a 20% solution of polyhexamethylene biguanide hydrochloride and the use concentration is listed as 0.2-1.0% of the 20% solution. This is equal to 0.04-0.2% or 400-2000 ppm of PHMB. Although an optimum pH of 4.0-8.0 is disclosed for "Cosmocil CQ", buffers are not  
35           suggested and no combinations of components are suggested for reducing the concentration of PHMB.

SUMMARY OF THE INVENTION

The present invention is based on the discovery that cosmetic formulations comprising various aqueous solutions, aqueous suspensions, powders, gels, creams, cakes, water base ointments, pastes and the like can be preserved with unexpectedly low concentrations of PHMB when a buffer is included in the formulation. In preferred formulations the concentration of PHMB is reduced even more by including components which are surprisingly synergistic with PHMB. The preserved cosmetic compositions of the present invention are especially suitable for use near the eyes. Not only do the compositions of the invention have a wide spectrum of bactericidal and fungicidal or bacteriostatic and fungistatic activity, because of the low concentration of PHMB which the invention makes possible, the novel compositions also are non-toxic and non-irritating to the skin.

This invention provides a non-toxic, non-irritating cosmetic composition which is preserved against microbial or fungal growth, the composition comprising an oil-in-water or water-in-oil emulsion, a microbicidally effective amount of a biguanide or water-soluble salt thereof, in combination with a buffer system, said biguanide having the formula:

(I)



wherein n is from 1 to 500.

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DESCRIPTION OF THE PREFERRED EMBODIMENTS

The biguanides for use in the present invention include hexamethylene biguanides, their polymers and water-soluble salts of such base compounds and polymers. Generally, the polymers have molecular weights of up to about 100,000 and are present in amounts from about 0.5 to about 100 parts by weight per hundred parts of the cosmetic composition. The antibacterial action of the biguanide-containing compositions described herein may also be supplemented by the addition of other germicidal agents. Because the overall germicidal activity of such combinations will in some instances be greater than when each is used separately, the concentration of total disinfectant in solution can be lowered, further reducing the potential adverse toxic reactions..

The compositions of the present invention are effective at low concentrations against a wide spectrum of microorganisms, including but not limited to S. epidermidis, C. albicans, A. fumigatus, etc. The compositions contain as their principal microbicide a biguanide of formula I, including low molecular weight oligomers where n averages from 4 to 7, high molecular weight long chain polymers up to approximately 100,000 M.W., as well as individual monomers of such polymers where n is 1. In addition the biguanides can be in the form of water-soluble salts of the free bases, such as hydrochloride and borate salts, acetate, gluconate, sulfonate, tartrate and citrate salts. Most conveniently,

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however, the water-soluble salts, e.g., hydrochloride, of the foregoing biguanides are used wherein the value for n generally averages between 2 and 12, and more specifically from 3 to 8. Thus, one preferred group of water-soluble biguanides described herein will have average molecular weights of at least 1,000 and more particularly from 1,000 to 50,000 M.W.

The range of polymeric and monomeric biguanides within the foregoing broad definition for use in the solutions of the present invention is surprising and unexpected, since polymers in the higher molecular weight ranges usually demonstrate lower toxicity levels than corresponding lower molecular weight materials. However, the monomer, e.g., hexamethylene biguanide hydrochloride, provides good bactericidal activity at low concentrations as does polyhexamethylene biguanide hydrochloride wherein n averages 4 to 7.

The above-disclosed biguanides and methods of preparation are described in the literature. For example, U.S. patent 3,428,576 describes the preparation of such biguanides from a diamine and salts thereof and a diamine salt of dicyanimide. This patent expressly teaches methods for making, e.g., the hydrochloride salt of polyhexamethylene biguanide which is also commercially available from ICI Americas, Inc., Wilmington, DE 19897, under the trademark Cosmocil CQ. For convenience, the biguanides described hereinafter for preserving cosmetic compositions shall be referred to as "PHMB".

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The cosmetic compositions of this invention contain a buffer, preferably a borate buffer, e.g., boric acid, sodium borate, potassium tetraborate, potassium metaborate or mixtures of the same. Surprisingly, a borate buffer is exceptionally effective in permitting the use of concentrations of PHMB in cosmetic compositions which are lower than would be microbicidally effective without a buffer or with other buffers.

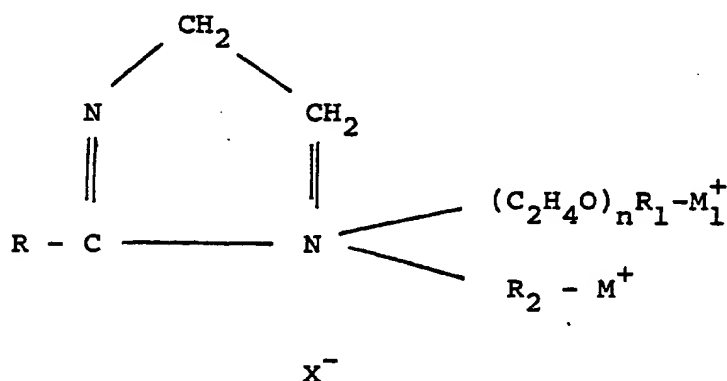
Applicants have additionally found that conventional buffers can be useful in this invention when those buffers are only used in conjunction with increased, but within concentrations of this invention, amounts of PHMB, an increased amount of sequestering agent, an amphoteric surfactant, a non-ionic surfactant or a cationic surfactant. The buffers in this category are sodium or potassium citrate, citric acid, sodium bicarbonate and various mixed phosphate buffers, including combinations of  $\text{Na}_2\text{HPO}_4$ ,  $\text{NaH}_2\text{PO}_4$  and  $\text{KH}_2\text{PO}_4$ . Generally, buffers may be used in amounts ranging from about 0.05 to about 2.5 percent, and more preferably, from about 0.1 to about 1.5 percent (w/w). Borate buffers yield best results with PHMB at concentrations from about 0.1 to about 2.5 weight percent for boric acid and about 0.10 to about 1.5 weight percent for sodium borate. Suitable sequestering agents include ethylene diaminetetraacetic acid (EDTA), gluconic acid, citric acid, tartaric acid and their salts, e.g., sodium. The foregoing surfactants, when employed as a buffer enhancer will be present in an amount from 0.0001 percent to 5.0 percent (w/w) percent to 5.0 percent (w/w).

The amphoteric charged surfactant molecule consists of a relatively complex organic portion with a net positive or negative charge. The latter charge is balanced by a positive or negative counterion; (e.g.,  $\text{Na}^+$ ,  $\text{Cl}^-$ ) which is not connected to the molecule by a covalent bond but is held in its environment by the attraction

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between the oppositely charged moieties. In the amphoteric molecule, the complex organic portion referred to above contains both positive and negative charges (at least one of each). As with the singly-charged molecule, electrical neutrality is provided by counterions, both negative and positive counterions being required for the same molecule. The uncharged portion of the amphoteric molecule contains hydrophobic groups (the charged portions usually function as a part of the hydrophilic groups) and may contain non-charged (i.e. non-ionic) hydrophilic groups.

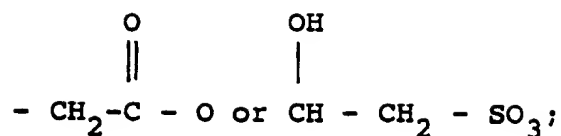
A preferred amphoteric surfactant molecule of this invention is illustrated by the following chemical structures:



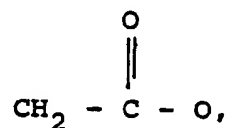
The structure is illustrated in the ionized form as it exists in aqueous media. In this structure, R represents a fatty acid radical of  $\text{C}_6$ - $\text{C}_{18}$ , e.g., coconut oil which is a mixture of lauric, myristic, oleic, stearic, palmitic and other similar acids; lauric acid; capric acid; caprylic and ethylhexoic acid; oleic acid; linoleic acid and stearic acid;  $\text{R}_2$  is



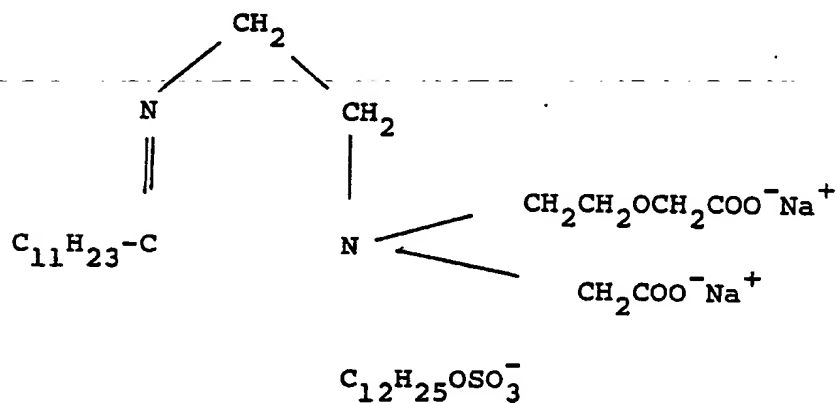
-7-



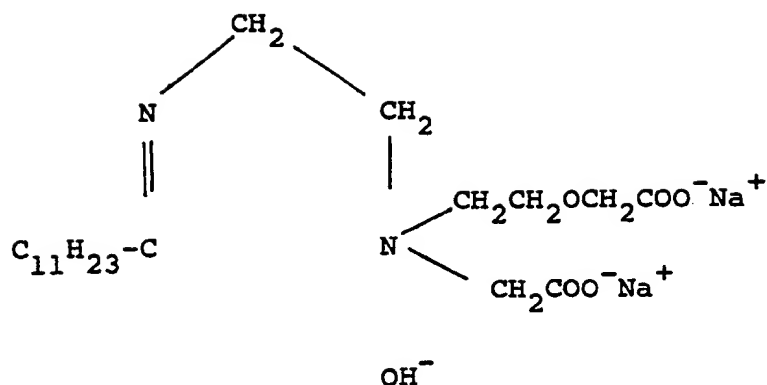
M and M<sub>1</sub> are cation salt forming groups, such as hydrogen or alkali metals, X is OH, or the acid group of an anionic surface active agent, e.g., sodium lauryl sulfate or sodium lauryl sulfonate, R<sub>1</sub> is H or



provided, however, when R<sub>1</sub> is hydrogen, M<sub>1</sub> is absent and n is an integer from 1 to 40. Materials of this type are offered commercially from the Miranol Chemical Co., Doyton, NJ 08810 under the trade name "Miranol." Typical examples of ionized amphoteric salts (commercial trade names Miranol 2MCA and C2M respectively) are shown below:

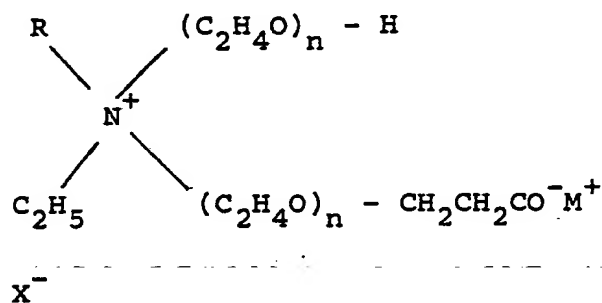


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Broadly, these compounds can be monocarboxylate, dicarboxylates or sulfonates. The counterions in the first example are  $\text{Na}^+$  and  $\text{CH}_{12}\text{H}_{25}\text{OSO}_3^-$  - and in the second example  $\text{Na}^+$  and  $\text{OH}^-$ .

Another class of amphoteric surfactants is given by the following chemical structure in the ionized form:

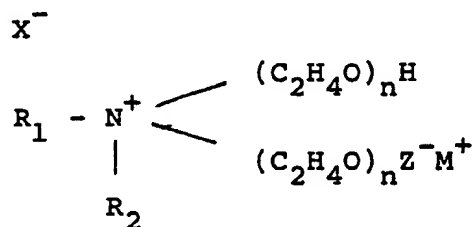


where R is a hydrophobe radical such as methyl octadecyl, methyl dodecyl, methyl octadecenyl, etc., M is an alkali metal, such as Na, K, etc. X is the negative part of an agent, such as  $\text{CH}_3\text{OSO}_3^-$ ,  $\text{C}_2\text{H}_5\text{OSO}_3^-$ , Cl, Br, etc.; n is an integer from 1 to 40. Materials of this type are

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available commercially from Armstrong Chemical Co., Inc., Janesville, WI 53545 under the trade name Sanac. This molecule has a nonionic functionality,  $(C_2H_4O)_nH$ . Specific examples are [2-(2-carboxyethyl) ethyl] [2-(2-hydroxyethyl)ethyl] methyloctadecylammonium methyl sulfate, potassium salt; [2-(2- carboxyethoxy) ethyl] [2-(2-hydroxyethoxy) ethyl] methyloctadecenylammonium methyl sulfate, potassium salt; and [2-(2- carboxyethoxy) ethyl] [2-(2hydroxyethoxy) ethyl] methylododecylammonium methyl sulfate, potassium salt.

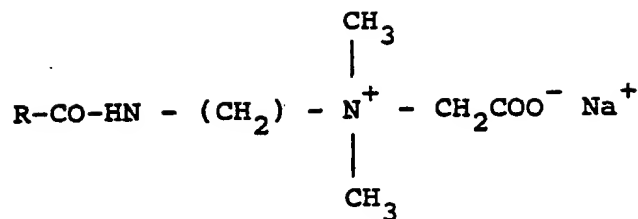
Another class of amphoteric surfactants may be exemplified by the following chemical structure, in the ionized form:



where  $R_1$  is a fatty acid radical or other hydrophobe radical,  $R_2$  is an alkyl or substituted alkyl radical,  $Z$  is a sulfate or sulfonic group, e.g.,  $-SO_4$ ,  $-CH_2CH_2SO_3$ ;  $M$  is an alkali metal such as Na or R,  $x$  is the negative radical from a quaternizing reagent such as  $CH_3OSO_3$ ,  $C_2H_5OSO_3$ , Cl, Br. etc.

Yet another class of amphoteric surfactants may be exemplified by the following chemical structure in the ionized form:

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Cl<sup>-</sup>

where R is alkylene having 12 to 13 atoms and R-CO- taken together as the acid radical such as coconut acid. Materials of this type are exemplified by cocoamidopropyl betaine commercially available from Stephen Chemical Co., Northfield, IL 60093 under the trade name Amphosol CA.

As suitable cationic surfactants, dual quaternary ammonium compositions are described in U.S. patent 3,525,793 and 3,472,939 and are commercially available from Onyx Chemical Company, Jersey City, NJ under the trademark BTS 2125M.

When used, neutral or non-ionic surfactants impart cleaning and conditioning properties and are usually present in amounts up to 15 weight percent. The surfactant should be soluble in the cosmetic composition, non-irritating to eye and other tissues and still usually have a hydrophilic-lipophile balance (HLB) of 12.4 to 18.8. Satisfactory non-ionic surfactants include polyethylene glycol esters of fatty acids, e.g., coconut, polysorbate, polyoxyethylene or polyoxypropylene ethers of higher alkanes (C<sub>12</sub>-C<sub>18</sub>). Examples of the preferred class include polysorbate 20 (available from ICI Americas Inc., Wilmington, DE 19897 under the trademark Tween 20), polyoxyethylene (23) lauryl ether (Brig® 35), polyoxyethylene (40) stearate (Myrj® 52), polyoxyethylene

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(25) propylene glycol stearate (Atlas® G 2612). Brij® 35, Myrj® 52 and Atlas® G 2612 are trademarks of, and are commercially available from ICI Americas Inc., Wilmington, DE 19897.

One non-ionic surfactant in particular, consisting of a poly (oxypropylene) -poly (oxyethylene) adduct of ethylene diamine having a molecular weight from about 7,500 to about 27,000 wherein at least 40 weight percent of said adduct is poly (oxyethylene), has been found to be particularly advantageous when used in amounts from about 0.01 to about 15 weight percent. The CTFA Cosmetic Ingredient Dictionary's adopted name for this group of surfactants is poloxamine. Such surfactants are available from BASF Wyandotte Corp., Wyandotte, Michigan, under the registered trademark "Tetronic". An analogous series of surfactants is the poloxamine series which is a polyoxyethylene, polyoxypropylene block polymers available from BASF Wyandotte Corp., Parsippany, NJ 07054 under the trademark "Pluronic".

Other amphoteric, cationic and non-ionic surfactants suitable for use in the invention can be readily ascertained, in view of the foregoing description, from McCutcheon's Detergents and Emulsifiers, North American Edition, McCutcheon Division, MC Publishing Co., Glen Rock, NJ 07452.

A second disinfectant/germicide can be employed as a solution preservative, but it may also function to potentiate, complement or broaden the spectrum of microbicidal activity of PHMB. This includes microbicidally effective amounts of germicides which are

compatible with and do not precipitate in the presence of PHMB, and comprises concentrations ranging from about 0.00001 to about 0.5 weight percent, and more preferably, from about 0.0001 to about 0.1 weight percent. Suitable complementary germicidal agents include, but are not limited to thimerosal, sorbic acid, 1,5-pentanediol, alkyl triethanolamines, phenylmercuric salts, e.g., nitrate, borate, acetate, chloride and mixtures thereof. Other germicidal compounds and salts may be used. Suitable salts are soluble in water at ambient temperature to the extent of at least 0.5 weight percent. These salts include the gluconate, isothionate (2-hydroxyethanesulfonate), formate, acetate, glutamate, succinate, monodiglycollate, dimethanesulfonate, lactate, diisobutyrate and glucoheptonate.

Further embodiments of potentiating or complementary disinfecting agents for use with PHMB also include certain quaternary ammonium compounds which possess a generally wide spectrum of bactericidal activity and wetting properties. Representative examples of the quaternary ammonium compounds are compositions comprised of balanced mixtures of n-alkyl dimethyl benzyl ammonium chlorides.

In cosmetic products, the PHMD buffer preservative systems are adequate at the level of from about 0.5 ppm to about 100 ppm to preserve the products by inhibiting microbial and fungal growth. Cosmetic products of particular interest within the scope of the instant

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invention include but are not limited to eye makeup remover, mascara and eye shadow. The PHMD buffer/preservative system works in aqueous solution, aqueous suspension, powders, gels, creams, cakes, water base ointments, pastes and the like. The buffer is preferably a borate, e.g., boric acid, sodium borate, potassium tetraborate, potassium metaborate or mixtures of the same.

Although the concentration of PHMB in the compositions of the invention can range from about 0.5 ppm to about 100 ppm, which is lower than the prior art suggests for cosmetic compositions containing PHMB, the concentration in cosmetic compositions having high solids content should be substantially above the lower end of the range. Thus, cosmetic creams, pastes, cakes, powders and the like have a substantially higher solids content than aqueous solutions and gels such as the aqueous eye makeup remover and the gel eye makeup remover described in examples hereinafter. In such compositions of higher solids content and in compositions of relatively high oil content the concentration of PHMB should be in the range from about 10 to about 100 ppm and preferably is in the range from about 40 to about 60 ppm. At these concentrations PHMB when used with a buffer such as borate is effective for preserving the compositions and the compositions are essentially nonirritating to the skin.

The PHMD preservative can be incorporated into the cosmetic formulations according to conventional procedures well known in the art. Typically, the formulation process depends upon the aqueous nature of the preservative system. For example, if the product has an oil phase, it may be desirable to create an oil-in-water emulsion.

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Nevertheless, the exact method of preparation is not critical to this invention.

The following examples are representative of cosmetic products within the object of this invention. These examples merely illustrate cosmetic formulations of the invention but are not intended to limit the scope thereof. The formulation processes employ conventional procedures well known in the art. Each of these compositions is non-toxic and non-irritating. More importantly, the formulas protect against the growth of microorganisms and fungi.

#### EXAMPLE I

An aqueous eye makeup remover is prepared with the following formulation:

	<u>Percent (w/w)</u>
Poloxamine 407 Surfactant	1.00
Lauroamphocarboxyglycinate	5.00
EDTA	0.11
Propylene glycol	5.00
Glycerine	5.00
Polyhexamethylene Biguanide HCl	1.1 ppm
Boric acid	0.80
Sodium borate	0.10
Purified Water	q.s. to 100.00



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EXAMPLE II

	<u>Percent (w/w)</u>
Poloxamine 407 Surfactant	22.00
Lauroamphocarboxyglycinate	4.00
EDTA	0.10
Polyhexamethylene Biguanide HCl	1.1 ppm
Boric acid	0.80
Sodium borate	0.15
Purified Water	q.s. to 100.00

A cream, eye makeup remover is prepared with the following formulation:

	<u>Percent (w/w)</u>
<u>Part A</u> Magnesium aluminum silicate	1.5
Purified Water	45.0
Propylene glycol	4.0
<u>Part B</u> Meroxapol 58	8.0
Meroxapol 314	4.0
Mineral oil	23.0
Trisolan LP <sup>1</sup>	2.5
Lanacet <sup>2</sup>	0.5
Vanseal CS <sup>3</sup>	0.5
Emulsifying Wax, N.F.	2.0
<u>Part C</u> Polyhexamethylene Biguanide HCl	75 ppm
Boric acid	0.8
Sodium borate	0.1
Purified water	q.s. to 100.0

1. Trade name of a mixture of isopropyl lanolate and lanolin, available from Emery Industries, Inc., Linden, NJ 07036.

2. Trade name of an acetylated lanolin, available from Emery Industries, Inc., Linden, NJ 07036.

3. Trade name of N-cocoyl sarcosine, available from R. T. Vanderbilt Co., Inc., Norwalk, CT 06855.

The product of Example III may be prepared by mixing the ingredients of Parts A, B and C separately. The mixtures of Parts A and B are then emulsified together. Part C is added to the emulsified material to produce the final product.

#### EXAMPLE IV

A cake mascara is prepared with the following formulation:

	<u>Percent (w/w)</u>
Beeswax	30.0
Mineral spirits 356	52.0
Iron oxide	5.0
Oat flour	2.0
Polyhexamethylene Biguanide HCl	50 ppm
Sodium borate	0.6
Purified Water	q.s. to 100.00

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A press powder eye shadow is prepared with the following formulation:

	<u>Percent (w/w)</u>
Talc	29.0
Zinc Stearate	8.0
Kaolin 10.0	
Oat flour	20.0
Titanium dioxide	10.0
Ultra pearl coloring agent	10.0
Dark blue coloring agent	10.0
Polyhexamethylene Biguanide HCl	50 ppm
Boric acid	0.80
Sodium borate	0.10
Purified water	q.s. to 100.0

EXAMPLE VI

A liquid eye shadow is prepared with the following formulation:

	<u>Percent (w/w)</u>
3516 ultra marine blue	5.10
Titanium dioxide	4.50
Pearl coloring agent	9.00
Polymer JR 30M*	0.60
Propylene glycol	10.00
Oat flour	2.00
Polyhexamethylene Biguanide HCl	50 ppm
Boric acid	0.80
Sodium borate	0.10
Purified water	q.s. to 100.00

\*Trade name of a cationic cellulosic resin, available from Union Carbide Co., Danbury, CT.

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In other preferred cosmetic compositions of the invention, a mixture of certain ingredients enhances the capacity of the PHMB preservative to withstand microbial insult and also widens the range of microorganisms against which the cosmetic composition is protected. Such a preferred composition contains, in addition to PHMB and the selected cosmetic ingredients, a second antimicrobial preservative such as diazolidinyl urea, the borate buffer system (sodium borate and boric acid) and an amphoteric or non-ionic surfactant. A preferred amphoteric surfactant is cocamidopropyl betaine and a preferred non-ionic surfactant is the poloxamine known as "Tetronic 1107" surfactant.

Preferred concentration ranges for the components of this kind of synergistic composition are:

PHMB	0.5 to 50 ppm
Borate (total of sodium borate and boric acid	0.1 to 1.5 wt. %
Surfactants	0.1 to 2.0 wt. %
Diazolidinyl urea	0.05 to 0.5 wt. %

While the invention has been described in conjunction with specific examples thereof, this is illustrative only. Accordingly, many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description and it is, therefore, intended to embrace all such alternatives, modifications and variations as to fall within the spirit and broad scope of the appended claims.

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What we claim is:

1. A nontoxic, nonirritating cosmetic composition preserved against microbial or fungal growth which contains a microbicidally or fungicidally effective amount of a biguanide or water-soluble salt thereof, in combination with a buffer, said biguanide having the formula:

wherein  $n$  is from 1 to 500, said biguanide being present in an amount from 0.5 to 100 parts by weight per hundred parts of said composition.

2. The composition of claim 1 wherein the biguanide is a water-soluble salt of polyhexamethylene biguanide.

3. The composition of claim 1 wherein  $n$  of the biguanide averages from 4 to 7.

4. The composition of claim 2 wherein the biguanide is present in an amount from 10 to 100 parts by weight per 100 parts of said composition.

5. The composition of claim 4 wherein the biguanide is present in an amount from 40 to 60 parts by weight per hundred parts of said composition.

6. The composition of claim 5 wherein the composition is a cosmetic cream, paste, powder or cake.

7. The composition of claim 2 wherein the buffer is a borate buffer.

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8. The composition of claim 7 wherein the buffer comprises about 0.1 to about 2.5 weight percent boric acid and about 0.10 to about 1.5 weight percent sodium borate.

# INTERNATIONAL SEARCH REPORT

International Application No PCT/US85/01880

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>3</sup> According to International Patent Classification (IPC) or to both National Classification and IPC INT. CL.4 A61K 7/021; C08J 3/00 U.S. CL. 523/105; 424/63; 514/635						
<b>II. FIELDS SEARCHED</b> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched <sup>4</sup></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 10px; vertical-align: top;">U.S.</td> <td style="padding: 10px; vertical-align: top;">523/105; 424/63; 514/635</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup></div>			Classification System	Classification Symbols	U.S.	523/105; 424/63; 514/635
Classification System	Classification Symbols					
U.S.	523/105; 424/63; 514/635					
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>						
Category <sup>6</sup>	Citation of Document, <sup>15</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No. <sup>18</sup>				
A	US, A, 4,014,676 PUBLISHED 13 APRIL 1976 CARTER					
A	US, A, 4,354,952 PUBLISHED 19 OCTOBER 1982 RIEDHAMMER ET AL					
A	US, A, 4,361,548 PUBLISHED 30 NOVEMBER 1982 SMITH ET AL					
P, Y	US, A, 4,478,821 PUBLISHED 23 OCTOBER 1984 CARRILLO	1-8				
A	DE, A1, 3334555 JOHNSON & JOHNSON 03 MAY 1984; see Abstract only					
A	EP, A1, 0041448 SALKIN N. 09 DECEMBER 1981 see Abstract only					
A	GB, A, 2074444 WITHERS & ROGERS 04 NOVEMBER 1981					
X, Y	GB, A, 1432345 SMITH & NEPHEW RESEARCH LIMITED 14 APRIL 1976, see pages 2-4.	1-8				
A	GB, A, 1464005 IMPERIAL CHEM INDS LTD. 09 FEBRUARY 1977, see Abstract only.					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><sup>15</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>						
<b>IV. CERTIFICATION</b>						
Date of the Actual Completion of the International Search <sup>9</sup> <div style="text-align: center; font-size: 1.2em;">28 OCTOBER 1985</div>		Date of Mailing of this International Search Report <sup>9</sup> <div style="text-align: center; font-size: 1.2em;">16 DEC 1985</div>				
International Searching Authority <sup>1</sup> <div style="text-align: center; font-size: 1.2em;">ISA/US</div>		Signature of Authorized Officer <sup>10</sup> <div style="text-align: center;"> <div style="text-align: center; font-weight: bold;">JUDY M. REDDICK</div> </div>				

## III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>	Relevant to Claim No <sup>18</sup>
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A	PRESERVATIVES DOCUMENTARY, PUBLISHED 1981 MARCH, S.M. HENRY AND GENE JACOBS "COSMETIC PRESERVATIVES", see pages 29-37..	
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